

BLOOD AND URINE COLLECTION

Prepared by the Laboratory for Clinical Biochemistry Research (LCBR) at the U of Vermont

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1. Background and Rationale

The Health ABC study involves the collection of approximately 75 mL of blood and a urine specimen from participants. Since the study depends on the voluntary return of participants over an extended period of time, every effort must be made to make the entire procedure as easy and painless as possible both for the participants and for the Field Center personnel.

A standard informed consent has been prepared for this study. With regard to laboratory procedures, the consent statement informs study participants that there is a small risk of bruising at the spot on the arm where the blood is taken and that about six tablespoons of blood are drawn. The consent statement also informs study participants that they will be contacted if clinically significant test results are discovered.

2. Equipment and Supplies

2.1 Sample ID Labels

You will be supplied with sheets of sample ID barcode labels to use for labeling forms, draw tubes, and cryovials. A sample sheet of barcode labels can be found in Appendix 1. All labels on each sheet have the same 6-digit sample ID number (the first digit identifies the clinic - Memphis = 1, Pittsburgh = 2).

There are 15 labels containing the ID number with no extension. Nine are to be used for pre-labeling the 9 draw tubes, with 3 extras for backup vacutainers. There is a label for the urine specimen cup and two labels for the tubes you will use to pool the EDTA-treated plasma samples and the serum samples. These labels have no barcode, and they have 1-3 lines of text indicating which specimen container they are intended for, including the stopper color and volume, if applicable.

There are also 2 barcoded labels with the ID number, one called "Phlebotomy Form," which is placed on the Phlebotomy Form (Appendix 2), and the other called, "Laboratory Processing Form" which is placed on the Laboratory Processing Form. ***This process of matching the participant-specific ID (already on the form brought to the lab by the participant) to the sample-specific ID barcode is crucial to being able to use the data collected from laboratory tests.***

There are also 6 barcoded labels with the same ID number and the words "BDID Form." Use of these labels is detailed in the Lab Specimen Processing chapter.

Finally, there are 49 labels intended for labeling cryovials (see Lab Specimen Processing chapter).

2.2 Blood Collection Trays and Tubes

Blood drawing trays are prepared in advance for the following day. Each tray is stocked with a full supply of blood drawing equipment for 6-9 participants and holds an ice bath and the individual blood collection tube rack for each participant. Several racks will also be prepared to hold various plastic tubes and vials for the final serum and plasma aliquots sent to the Laboratory for Clinical Biochemistry Research (LCBR) for analysis. The blood collection tube racks and aliquot tube racks are prelabeled from the same sheet of sample ID barcode labels.

2.2.1 Blood collection tray. The collection tray itself is made of hard plastic which is unbreakable and can be easily cleaned. The tray has ten individual compartments which are filled with the following supplies:

Alcohol swabs	Smelling salts
Band-Aids	Timer/stopwatch
Gauze	Scissors
Tourniquets (2)	Adhesive tape
Vacutainer holders	Pencils/pens
Needle/sharps container	Latex gloves
Styrofoam ice bath filled ~10 min before draw	
21G Butterfly needles with Luer adapter	

2.2.2 Blood Collection Rack: Labeling and Setup. A separate tube rack containing the necessary draw tubes is set up for each participant. They are arranged according to the priority of the draw. This rack will fit into the blood collection tray. The blood collection tubes should be prelabeled with sample ID labels. After the labels have been used for setting up the blood collection rack and the aliquot rack (see Lab Specimen Processing chapter), there will be 13 labels left: 3 "Backup Vacutainer" labels, 1 "Phlebotomy Form" label, 1 "Laboratory Processing Form" label, 2 labels for the tubes used to pool plasma and serum, and 6 "BDID Form" labels. These can be separated into 2 mini-sheets: The "Backup Vacutainer," "Phlebotomy Form," and "Laboratory Processing Form" labels should be clipped to the corresponding blood collection tray. The labels for the pooling tubes and the "BDID Form" labels should be clipped to the corresponding aliquot rack.

2.2.3 Description of Blood Collection Tubes Each draw tube is color coded to aid in handling.

NOTE: Tubes #9 and #10 are used to collect extra blood as needed for the study. The amount taken can be 5 mL for tube #9 and #10, or 10 mL of just #9 or 10 mL of just #10, depending upon shortfalls of serum or plasma.

Tubes 1, 5, 6, and 9 are 10 mL siliconized red stoppered tubes. Tube 9 is a 10 mL or a 5 mL siliconized red stoppered tube. These tubes contain no anticoagulant so that the blood clots to form serum. After drawing, the blood is allowed to clot at room temperature for *40-45* minutes (Maximum = 90 minutes). The serum is used for analysis of glucose, insulin, albumin, alkaline phosphatase, and creatinine.

Tubes 2 and 7 are 10 mL lavender stoppered tubes containing a 15% EDTA as the anticoagulant. Tube 10 is either a 10 mL or 5 mL lavender stoppered tube containing a 15% EDTA solution. After drawing, the tubes are mixed and immediately placed on ice. The plasma will be used for cholesterol, and the buffy coat is collected for DNA analysis into a clear-capped 2.0 mL cryovial. Red cells (2.0 mL volume) are also collected in a white-capped cryovial.

Tube 3 is a 5 mL red stoppered "Special Coagulation"/SCAT-I tube provided by LCBR. It contains a special combination of anticoagulants that ensure long-term stability of the plasma sample. Specifically, this tube, when filled, will contain 4.5 NM EDTA, 150 KIU/mL aprotinin, and 20 μ M D-Phe-Pro-Arg-chloroketone. It is critical that this tube is mixed well (>30 seconds of gentle inversion) before being placed on ice to await future processing. NOTE: This tube contains a white powdered anticoagulant.

2.2.3.1 Special considerations for SCAT-I tubes

- *This tube must be stored refrigerated until used.* (It may be left out overnight after labeling, but should be re-refrigerated if not used the next day).
- This tube must be drawn after at least one other tube (in this case, one serum and one plasma tube)
- This tube is non-sterile. It must be drawn using a butterfly apparatus with 12 inches of tubing between the needle and the tube.
- Care should be taken to avoid hemolysis. The tube should be angled so that the blood flows down the side of the tube, rather than allowing the blood to splash against the bottom.

Tube 4 is a 4.5 mL blue stoppered tubes containing 0.5 mL of 3.8% sodium citrate. After drawing, this tube is mixed and immediately placed on ice. Plasma from this tube will be stored in repository.

Tube 8 is a 5 mL siliconized, red stoppered tube used for the 2-Hr OGTT collection. The serum is used for 2-Hr glucose measurements. ***Since this tube will be separated from the rest of the draw tubes after the fasting phlebotomy, the participant's name should be written on it to avoid using the wrong tube two hours later.***

3. Safety Issues and Exclusions

3.1 Precautions for Handling Blood Specimens In accordance with the OSHA regulations on blood borne pathogens (see Appendix 4 for complete OSHA regulations), the LCBR recommends the following laboratory safety protocol for the field center laboratories:

- Non-permeable lab coats, latex gloves, and face shields should be used when handling any blood in any situation where splashes, spray, spatter, or droplets of blood may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
- 'Universal Precautions' should be followed when handling any blood products.
- Contaminated needles and sharps shall be immediately placed in a puncture-resistant, leakproof container. Never recap or break needles.
- Hepatitis B vaccine should be offered to all unvaccinated technicians handling blood and documentation of vaccination or technician's declining to be vaccinated should be kept

3.2 Participant Precautions and Exclusions

3.2.1 Participant Phlebotomy Questionnaire Following the questionnaire format on the Phlebotomy Form, each participant is asked whether they have a bleeding disorder before the blood is drawn (Ques. 1). If they have had any problems with excessive bleeding or bruising at a venipuncture site, use your own judgment to decide whether or not a clinic physician or nurse supervisor should be consulted.

There is no action to take if the participant has been told they have a coagulation disorder (Ques. 2).

If the participant has experienced fainting spells during phlebotomy (Ques. 3), ask the participant the frequency of fainting spells. If the participant frequently faints, again, use your own judgment to determine whether or not a consultation with the clinic physician or nurse supervisor is necessary. Provide smelling salts, basin, and a cold cloth if needed. See section below on precautions when a participant feels faint.

3.2.2 PRECAUTIONS WHEN A PARTICIPANT FEELS FAINT OR LOOKS FAINT FOLLOWING THE BLOOD DRAWING.

- Have the participant remain in the chair, if necessary have them sit with their head between their knees.
- Provide the participant with a basin if they feel nauseated.
- Have the participant stay sitting until the color returns and they feel better.
- Place a cold wet cloth on the back of the participant's neck.
- If the participant faints, use smelling salts to revive by crushing the ampule and waving it under the participant's nose for a few seconds.
- If the participant continues to feel sick, contact a medical (nursing) staff member who will advise you on further action.

3.3 Participant Refusal to Provide Urine Sample or Refusal of Phlebotomy

Rarely, a participant will refuse to provide a urine sample or will refuse phlebotomy. Please keep a list of Health ABC Enrollment ID #s of any of these participants and identify which test they refused.

4. Subject and Exam Room Preparation

4.1 Phlebotomy Room

The blood drawing should take place in an isolated room or participants should be separated by room dividers. The room should be equipped with all of the necessary blood drawing supplies. A separate counter or work table should be equipped with all of the materials and vials that are used in the blood handling and processing. The centrifuge, refrigerator, and freezer should be nearby.

4.2 Preparation for Phlebotomy

Preparation for phlebotomy is done in the following manner. Early morning, before any participants arrive:

- Check to make sure that blood collection tray is properly equipped. Every item on the checklist (Appendix 5) must be ready before proceeding.

- Check that each vacutainer tube is properly labeled with sample ID labels and numbered 1-9 (note 9 is drawn before 7).
- Check that the sample processing station is properly equipped (see Lab Sample Processing chapter).
- Make sure the phlebotomy room is tidy and stocked with extra smelling salts, basin, and disposable wash cloths, and that blood mixer is functional.

Approximately 10 minutes before scheduled participant arrival:

- Fill styrofoam ice bath 3/4 full with crushed ice.

4.3 Preparation of Participants for Urine Collection

Urine will be collected on all participants whenever possible. Collection will be random and therefore considered a 'spot' urine collection. *Urine should be collected before the glucose load and before venipuncture.* Samples should not be collected after exertion or an acute fluid load.

Female participants will use the Sage Commode Specimen & Measuring System #2500. Follow the instructions provided with this collection kit. Male participants may urinate directly into a specimen collection container.

Containers for routine random specimens should be chemically clean, should hold about 50 mL in volume, and must have a tight-fitting lid to prevent leakage during transportation.

4.3.1 Instructions for Participants:

4.3.1.1 Females: The participant's privacy should be assured. She should perform the following steps:

1. Have equipment ready.
2. Remove the cap from the collection container.
3. Void directly into the collection container until half full.
4. Carefully seal the cap of the container so that it is tight and leak proof.

4.3.1.2 Males: The participant's privacy should be assured. He should perform the following steps:

1. Have all equipment ready.

2. Void directly into the collection container until half full.
3. Carefully seal the cap of the container so that it is tight and leak proof.

4.4 Preparation of Participants for Phlebotomy

It should be stressed that this study requires the voluntary cooperation of the participants. These people are donating both time and blood on a purely voluntary basis, with no reward other than the knowledge that they are contributing to progress in medicine. Thus, the whole experience must be made as pleasant as possible. Nine tubes of blood of various sizes are collected. The smallest tubes contain less than 1 teaspoon, while the largest tube contains slightly over 2 teaspoons (10 mL) of blood. Any participants who are concerned about the volume of blood should be reassured that the total amount of blood drawn is less than 7 tablespoons, although it may look like more. The phlebotomist may also assure participants that they donate 7 times as much blood (450 mL) when they donate a unit of blood.

5. Detailed Procedures

5.1 Forms

An example of the Phlebotomy form is in Appendix 2. The purpose of this form is to provide a vital link between the sample ID# and the participant ID# and to facilitate the collection of plasma and serum samples from participants. The collection must be done in a rapid and efficient manner, with maximum protection for the participant. In addition, the process must facilitate the monitoring of phlebotomy and other quality assurance parameters. All forms must be completed in ink.

The Phlebotomy form has the following purposes:

1. Assure the most efficient and safest possible venipuncture for participants.
2. Allow the monitoring of the quality of the above procedures.
3. Allow more efficient processing of the samples at LCBR.
4. Provide information critical to the interpretation of the assay results

The participant will arrive at the phlebotomy station with their with their Health ABC participant ID# already filled in on their Phlebotomy, Oral Glucose Tolerance Test, and Laboratory Processing forms. The sample ID will be determined by the set of prelabeled tubes and urine collection cup used to collect their samples. It is vital that this same sample ID be matched up with the participant ID on both the Phlebotomy and the Laboratory Processing forms (see Lab Specimen Processing chapter). There will be a small sheet of labels clipped to the rack of vacutainers. On

it is a “Phlebotomy Form” label, to be affixed to the upper right corner of the Phlebotomy Form, and a “Laboratory Processing Form” label which should be affixed to the upper right corner of the Laboratory Processing Form. This should be done before drawing any blood, to insure that this critical task is not forgotten.

There are actually two parts to the Phlebotomy form associated with blood drawing. The first section contains questions that are important for participant safety; these questions should be asked immediately before phlebotomy and deal with any propensity to bleed or faint. The second part deals with details of the phlebotomy procedure, whether it went smoothly, how long it took, etc.

5.1.10 Return Visit Aliquots

Occasionally, participants return to the clinic just to give a urine sample or have a fasting blood draw and oral glucose tolerance test. There are new forms that must be filled out for return visits: the Return Visit Phlebotomy Form, the Return Visit Oral Glucose Tolerance Form, and the Return Visit Lab Processing Form (see Appendix 3). Use a new set of sample ID bar code labels. Place the Phlebotomy Form label in the Bar Code Label space on the Return Visit Phlebotomy Form. Place a Laboratory Processing Form label in the Bar Code Label space on the Return Visit Laboratory Processing Form. Use the draw tube labels for Draw Tube 1, 2, and 8; and the urine specimen cup label for the urine specimen. Use the cryovial labels for blood (for cryovials 01, 02, 25, 26, and 46) and urine cryovials (47, 48, and 49) as usual. Be sure to fill out all three forms with the header information including the Health ABC ID #, Acrostic, Date Form Completed, and Staff ID #.

5.2 Phlebotomy

5.2.1 General. Blood drawing is standardized for the sitting position.

The venipuncture is performed with a 21 gauge butterfly needle with 12 inches of plastic tubing between the venipuncture site and the blood collection tubes. A 23 gauge needle may be used, if necessary, for a difficult draw, *but this must be noted on the P/P form under “Comments on blood collection.”* The butterfly has a small, thin-walled needle, which minimizes trauma to the skin and vein. The use of 12 inches of tubing allows tubes to be changed without any movement of the needle in the vein. If the participant is concerned about the venipuncture, he/she may be reassured to know such care is taken. The participant should be given enough time to feel comfortable both before and after the blood collection. In many cases the most memorable part of the experience for the participant will be the contact with the technician who draws the blood and their general attitude and competence.

If the participant is nervous or excited, the technician briefly describes the procedure. Sample script: *"I am going to be drawing about 7 tablespoons of blood. This blood will be used in tests for lipids and cholesterol and chemistries. We hope to be able to use the results of these tests to better understand health and disease in older people."*

5.2.2 Handling participants who are extremely apprehensive about having blood drawn. *Do not under any circumstances force the participant to have blood drawn.* It may help to explain to the participant that the blood drawing is designed to be as nearly painless as possible. It is sometimes best to let the participant go on with another part of the visit. It may also be helpful to have the participant relax in the blood drawing chair just so the phlebotomist can check the veins in the participant's arms, without actually drawing blood. If the participant has "good veins" the phlebotomist can reassuringly say, "Oh, you have good veins; there should be no problem." Elderly patients are often aware of the difficulty they pose to phlebotomists and should receive extra consideration and detailed explanations as required.

5.2.3 Venipuncture Procedure

- Wear Latex gloves and a lab coat.
- Arrange draw tubes in order of draw (see below) on the table top within easy reach. Assemble butterfly apparatus and vacutainer holders, gauze, and alcohol prep prior to tourniquet application.
- Apply tourniquet.
- Examine participant's arms for the best site for venipuncture. Generally the antecubital vein is preferred, if feasible. Release tourniquet.
- Cleanse venipuncture site. Prepare area by wiping with alcohol swab in a circular motion from center to periphery. Allow area to dry.
- Reapply tourniquet and start timer. Note the start time on the Phlebotomy form.
- Grasp the participant's arm firmly, using your thumb to draw the skin taut. This anchors the vein. The thumb should be 1 or 2 inches below the venipuncture site.
- With the needle bevel upward, enter the vein in a smooth continuous motion.
- Make sure the participant's arm is in a flat or downward position while maintaining the tube below the site when the needle is in the vein. It may be helpful to have the participant make a fist with the opposite hand and place it under the elbow for support.
- Grasp the flange of the vacutainer holder and push the tube forward until the butt end of the needle punctures the stopper, exposing the full lumen of the needle.
- Note the blood flow into the first collection tube. If blood is flowing freely, the butterfly needle can be taped to the participant's arm for the duration of the draw. If the flow rate is very slow, the needle may not be positioned correctly.

- Remove the tourniquet at 2 minutes. Once the draw has started, do not change the position of the tube until it is withdrawn from the needle. If blood flow ceases after the tourniquet is removed, it may be reapplied for another 2 minutes. Note on the Phlebotomy form the total length of time the tourniquet was on.
- Keep a constant, slight forward pressure (in the direction of the needle) on the end of the tube. This prevents release of the shutoff valve and stopping of blood flow. Do not vary pressure or reintroduce pressure after completion of the draw.
- Fill each vacutainer tube as completely as possible; i.e., until the vacuum is exhausted and blood flow ceases. If a vacutainer tube fills only partially, remove the vacutainer and attach one of your extra, backup tubes of the same type without removing the needle from the vein. Be sure to place one of the "Backup Vacutainer" labels on that tube after completing phlebotomy.
- When the blood flow ceases, remove the tube from the holder. The shutoff valve re-covers the point, stopping blood flow until the next tube is inserted.
- As each tube is removed, mix by gently inverting before placing tube on the mixer. Note: do NOT mix red top tubes 1, 5, 6, and 9. (See section on Blood Mixing During Venipuncture below).
- Average venipuncture time is 3-6 minutes, but any difficulties may increase this time to 10 or 15 minutes. Be sure to note the time venipuncture is completed on the Phlebotomy form.

5.2.4 Removing the Needle

- To remove the needle, lightly place clean gauze over venipuncture site. Remove the needle quickly and immediately apply pressure to the site with a gauze pad. Discard needle into puncture-proof sharps container.
- Have the participant hold the gauze pad firmly for one to two minutes to prevent a hematoma.
- Remove tubes from the blood mixer and place in ice (#2, 3, 4, & 7). Tubes #1, 5, 6 & 9 should already be in the rack at room temperature.

5.2.5 Bandaging the Arm

Under normal conditions:

- Slip the gauze pad down over the site, applying mild pressure.
- Apply an adhesive or gauze bandage over the venipuncture site after making sure that blood flow has stopped.
- Tell the patient to leave the bandage on for at least 15 minutes.

If the patient continues to bleed:

- Apply pressure to the site with a gauze pad. Keep the arm elevated until the bleeding stops.
- Wrap a gauze bandage tightly around the arm over the pad.
- Tell the patient to leave the bandage on for at least 15 minutes.

5.2.6 Completing the Blood Drawing Procedure

- Dispose of needle and tubing in the appropriate biohazard needle sharps containers.
- Dispense the glucola for the oral glucose tolerance test, if indicated (see Oral Glucose Tolerance Test chapter). If the participant is ineligible for the oral glucose tolerance test, make the following notations on the Phlebotomy and Laboratory Processing forms:
 - If the participant uses insulin, put an X in the box labeled N/A next to cryovial 26 on the Laboratory Processing form (this cryovial will not be filled).
 - If no two-hour blood draw will be done, put an X in the box labeled N/A next to cryovial 46 on the Laboratory Processing form (this cryovial will not be filled).
- Complete the first page of the Phlebotomy form. This includes rating the venipuncture as clean or traumatic and writing any comments about any difficulties with the phlebotomy under “Comments on Phlebotomy”.
- Clean up the venipuncture area (if necessary).
- Bring blood collection tray to the processing area with the filled vacutainer tubes and Laboratory Processing form.

5.2.7 Procedures for Difficult Draw

If a blood sample is not forthcoming, the following manipulations may be helpful.

- If there is a sucking sound, turn needle slightly or lift the holder in an effort to move the bevel away from the wall of the vein.
- If no blood appears, move needle slightly in hope of entering vein. Do not probe. If not successful, release tourniquet and remove needle. A second attempt can be made on the other arm.
- Loosen the tourniquet. It may have been applied too tightly, thereby stopping the blood flow. Reapply the tourniquet loosely. If the tourniquet is a velcro type, quickly release and press back together. Be sure, however, that the tourniquet remains on for no longer than two minutes at a time.
- DO NOT attempt a venipuncture more than twice unless a participant encourages you to do so.

- Reassure the participant that the inability to obtain a clean venipuncture is not any sign of a medical problem on their part.
- If venipuncture is unsuccessful, participant should be rescheduled at a later date, preferably with a different Field Center phlebotomist.
- Document any problems with venipuncture and sample collection on the Phlebotomy form. In particular, note whether a vein other than one of the antecubital veins was used.

5.2.8 Other Possible Problems

1) Not all tubes are collected (blood flow ceases, difficult venipuncture, etc.): *Always fill the collection tubes in the order specified.* Make notations of difficulties on the Phlebotomy form. If the participant is willing, another attempt should be made to complete the draw.

2) Collection tube does not fill: First, try another tube of the same type. Partially filled plasma tubes are not acceptable if less than 2/3 full. Partial tubes for serum are okay, but will result in a reduced number of aliquots. Check "No" (not filled to capacity) and explain why under Question 8 of the Phlebotomy form if a tube is not completely filled.

5.2.9 Priority of Tubes

A total of approximately (70-75) mL of blood will be drawn from each participant in 9 tubes. Tubes are numbered 1-9 (or 10) and arranged in the rack to be drawn in the following order of priority:

	1.	Serum 10 mL	red top
	2.	EDTA 10 mL	lavender top
	3.	SCAT-I 5 mL	red top
	4.	Citrate 4.5 mL	blue top
	5.	Serum 10 mL	red top
	6.	Serum 10 mL	red top
	(9.)	Extra Serum 5 or 10 mL	red top
	7.	EDTA 10 mL	lavender top
	(10.)	Extra EDTA 5 or 10 mL	lavender top
2-Hr	8.	Serum 5 mL	red top

5.3 Blood Mixing During Venipuncture

Each tube should be treated as follows:

- #1, 5, 6, (9) Serum: do NOT mix; place in rack at room temperature for AT LEAST 40 minutes
- #2 & 7 (10) EDTA: place on mixer for ~30 seconds, then place in ice bath
- #3 SCAT-I: place on mixer for AT LEAST 30 seconds, then place in ice bath
- #4 Citrate: place on mixer for ~30 seconds, then place in ice bath
After OGTT (if applicable):
- #8 Serum: do NOT mix; place in rack at RT for AT LEAST 40 minutes.

6. Procedures for Performing the Measurements at Home

This examination is not feasible for home visits.

7. Alert Values/Follow-up

Laboratory results are reported by the central laboratory to the field centers by mail within 14 days. Two copies of the report are sent, one for the participant's file and one to be sent to the participant. If an abnormal value (see "Immediate Alerts" in the following table) is detected, however, the central laboratory notifies the field center by both phone and fax.

Analyte	Reference Range for Reports		Immediate Alerts*
Lipids:			
Cholesterol	<200 mg/dL 200-239 mg/dL >239 mg/dL	Normal Borderline Elevated**	None
Triglyceride	60-250 mg/dL		>1000 mg/dL
HDL-C	≥35 mg/dL		None
LDL-C	<130 mg/dL 130-159 mg/dL >159 mg/dL	Normal Borderline Elevated**	None
Glucose Metabolism:			
Fasting Glucose	<115 and ≥50 mg/dL 115-139 mg/dL ≥140 mg/dL	Normal Borderline Elevated**	>350 mg/dL OR <50 mg/dL
2-Hr Glucose	<140 and ≥50 mg/dL 140-199 mg/dL ≥200 mg/dL	Normal Borderline Elevated**	>500 mg/dL OR <50 mg/dL
Fasting Insulin	We will not report values to participant or physician		
General Chemistries:			
Creatinine	0.7-1.5 mg/dL		>3.0 mg/dL
Albumin	3.0-5.5 mg/dL		None
Alkaline Phosphatase	40-140u/L†		>350 u/L
Hg A ₁ C	4-6% Greater than 7% may indicate prior or current elevated glucose levels.		None

*Central Lab calls Field Centers. Field center notifies participant and participant's physician by telephone/fax if participant has granted permission to notify physician. Use modified letter from CHS (see Appendix 6) with abnormal value filled in.

**Notify participant and participant's physician by fax/letter if participant has granted permission to notify physician. Use modified letter from CHS with abnormal value filled in.

Occasionally, an error value is reported for a particular laboratory result. The two most common error values are:

-999, which indicates that no sample was received for that test. This may be expected, as when a glucose tolerance test is not run because a participant is diabetic, or may indicate a shipping error by the field center. If the field center believes that a sample was sent, LCBR should be notified and the source of the error determined.

-777, which indicates that the test was run, but a valid result could not be obtained. This error may come about in a variety of ways. Sometimes an incomplete aliquot may have been sent by the field center and there is insufficient sample to run the test. A very high triglyceride result (>400 mg/dL) makes it impossible to

calculate a value for LDL, which will then be reported as -777. When -777 is reported for hemoglobin A₁C, it may either indicate that the whole blood sample was received in unusable condition (improper handling such as freezing) or that an abnormal hemoglobin variant was detected. The lab can identify S and F abnormalities and report a result. Hemoglobins C, D, E, G, and J cannot be differentiated except by further, more expensive testing beyond the scope of this study. Since hemoglobins D, E, G, and J shorten red blood survival and give erroneously low hemoglobin A₁C values, samples with these hemoglobin variants are reported as abnormal with no result (-777). Although hemoglobin C does not shorten red blood cell survival, since it can't be positively differentiated from D, E, G, and J, the hemoglobin A₁C value cannot be verified and is also reported as -777.

8. Quality Assurance

8.1 Training Requirements

Clinical experience with phlebotomy is mandatory. Additional training should include:

- Read and study manual
- Attend Health ABC training session on techniques (or observe procedure by experienced examiner)
- Discuss problems and questions with local expert or QC officer

8.2 Certification Requirements

- Complete training requirements
- Explain what to do for difficult venipuncture
- Recite measures to take for fainting participant
- Conduct phlebotomy on volunteer or participant while being observed by QC officer using QC checklist

8.3 Quality Assurance Checklist

Preparation:

- ☐ Blood collection trays properly prepared
- ☐ Blood draw tubes properly labeled
- ☐ Questions on Phlebotomy form asked
- ☐ Proper instructions given for urine collection

- ☐ Hepatitis B vaccination given or offered to all personnel handling blood

Venipuncture properly carried out:

- ☐ Script properly delivered
- ☐ Non-permeable lab coats, gloves, and face shields used
- ☐ Preparation of venipuncture site correctly done
- ☐ Venipuncture smoothly done
- ☐ Tubes filled in proper priority order
- ☐ Plasma tubes at least 2/3 full
- ☐ Tourniquet removed at 2 minutes
- ☐ Needle removed and arm bandaged correctly
- ☐ Needle and tubing appropriately disposed

Tubes mixed and handled correctly after filling:

- ☐ Tubes 1, 5, 6, & 9 NOT mixed, placed in rack at room temperature
- ☐ Tubes 2, 3, 4, 7 (10) mixed for at least 30 seconds, placed in ice bath
- ☐ Tube 8 (OGTT) NOT mixed, placed in rack at room temperature


































Phlebotomy form properly filled out:

- ☐ Sample ID barcode label affixed to upper right corner (and to upper right corner of Lab Processing form)
- ☐ Time at start of venipuncture entered
- ☐ Time at end of venipuncture entered
- ☐ Total elapsed time with tourniquet entered
- ☐ Quality of venipuncture checked
- ☐ Question 8 filled out for both blood and urine collection
- ☐ Total fasting time correctly calculated
- ☐ N/A box for cryovial 26 checked on Lab Processing form, if participant taking insulin
- ☐ N/A box for cryovial 46 checked on Lab Processing form, if OGTT not administered


APPENDIX 1 **Sample Label Sheet (Bar Codes)** **(page 1 of 2)**

Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.
123456 Draw Tube 1 Red top 10 ml	123456 Draw Tube 2 Purple top 10 ml	123456 Draw Tube 3 SCAT-I 5 ml	123456 Urine cup	123456 Serum Pool 20 ml	123456 Plasma Pool 15 ml	123456-05 W/EDTA 0.5	123456-06 W/EDTA 1.0	123456-07 W/EDTA 1.0
Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.
123456 Draw Tube 4 Blue top 4.5 ml	123456 Draw Tube 5 Red top 10 ml	123456 Draw Tube 6 Red top 10 ml	123456 bd ID Form	123456 bd ID Form	123456 bd ID Form	123456-08 W/EDTA 1.0	123456-09 W/EDTA 1.0	123456-10 W/EDTA 0.5
Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.
123456 Draw Tube 7 Purple top 10 ml	123456 Draw Tube 8 Red top 5 ml	123456 Backup Vacutainer	123456 bd ID Form	123456 bd ID Form	123456-01 W/0.5 whole blood To LCBR DO NOT FREEZE	123456-11 W/EDTA 0.5	123456-12 W/EDTA 0.5	123456-13 W/EDTA 0.5
Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.	Place this end on vial first.
123456 Backup Vacutainer	123456 P/P Form	123456 P/P Form	123456-02 W/EDTA 1.0 To LCBR	123456-03 W/EDTA 0.5	123456-04 W/EDTA 0.5	123456-14 W/EDTA 0.5	123456-15 C/Bufy	123456-16 W/Cells 2.0

APPENDIX 1
Sample Label Sheet (Bar Codes)
(page 2 of 2)

Place this end on vial first.  123456-17 Y/SCAT 0.5	Place this end on vial first.  123456-18 Y/SCAT 0.5	Place this end on vial first.  123456-19 Y/SCAT 0.5	Place this end on vial first.  123456-29 R/Serum 0.5	Place this end on vial first.  123456-30 R/Serum 0.5	Place this end on vial first.  123456-31 R/Serum 0.5	Place this end on vial first.  123456-41 R/Serum 0.5	Place this end on vial first.  123456-42 R/Serum 0.5	Place this end on vial first.  123456-43 R/Serum 0.5
Place this end on vial first.  123456-20 Y/SCAT 0.5	Place this end on vial first.  123456-21 B/Citrate 0.5	Place this end on vial first.  123456-22 B/Citrate 0.5	Place this end on vial first.  123456-32 R/Serum 0.5	Place this end on vial first.  123456-33 R/Serum 0.5	Place this end on vial first.  123456-34 R/Serum 1.0	Place this end on vial first.  123456-44 R/Serum 0.5	Place this end on vial first.  123456-45 R/Serum 0.5	Place this end on vial first.  123456-46 Q/OGTT 0.5 To LCBR
Place this end on vial first.  123456-23 B/Citrate 0.5	Place this end on vial first.  123456-24 B/Citrate 0.5	Place this end on vial first.  123456-25 R/Serum 0.5 To LCBR	Place this end on vial first.  123456-35 R/Serum 1.0	Place this end on vial first.  123456-36 R/Serum 1.0	Place this end on vial first.  123456-37 R/Serum 1.0	Place this end on vial first.  123456-47 V/Urine 2.0	Place this end on vial first.  123456-48 V/Urine 2.0	Place this end on vial first.  123456-49 G/Acid 2.0
Place this end on vial first.  123456-26 R/Serum 0.5 To LCBR	Place this end on vial first.  123456-27 R/Serum 0.5	Place this end on vial first.  123456-28 R/Serum 0.5	Place this end on vial first.  123456-38 R/Serum 1.0	Place this end on vial first.  123456-39 R/Serum 1.0	Place this end on vial first.  123456-40 R/Serum 0.5			

APPENDIX 2
Phlebotomy Form



PHLEBOTOMY

Bar Code Label

Staff ID #

1 Do you bleed or bruise easily?
☐ Yes ☐ No ☐ Don't know

2 Have you ever been told you have a disorder relating to blood clotting or coagulation?
☐ Yes ☐ No ☐ Don't know

3 Have you ever experienced fainting spells while having blood drawn?
☐ Yes ☐ No ☐ Don't know

4 Time at start of venipuncture:

:

☐ am ☐ pm

Hours Minutes

Was any blood drawn?
☐ Yes ☐ No

↓

Please describe why not?

- Do NOT administer OGTT.
- Check N/A box next to #46 on Laboratory Processing Form.

7 Quality of venipuncture:
☐ Clean ☐ Traumatic

↓

☐ Vein collapse
☐ Hematoma
☐ Vein hard to get
☐ Multiple sticks

☐ Excessive duration of draw
☐ Leakage at venipuncture site
☐ Other *(Please specify)*

5 Time blood draw completed:

:

☐ am ☐ pm

Hours Minutes

8 Were tubes filled to specified capacity?
 If not, comment why.

Blood Volume/Tube	Filled to Capacity?	Comment
	Yes	No
1. Serum 10ml	<input type="checkbox"/>	<input type="checkbox"/>
2. EDTA 10ml	<input type="checkbox"/>	<input type="checkbox"/>
3. SCAT-I 5ml	<input type="checkbox"/>	<input type="checkbox"/>
4. Citrate 4.5ml	<input type="checkbox"/>	<input type="checkbox"/>
5. Serum 10ml	<input type="checkbox"/>	<input type="checkbox"/>
6. Serum 10ml	<input type="checkbox"/>	<input type="checkbox"/>
9. Extra Serum	<input type="checkbox"/>	<input type="checkbox"/>
7. EDTA 10ml	<input type="checkbox"/>	<input type="checkbox"/>
10. Extra EDTA	<input type="checkbox"/>	<input type="checkbox"/>
Urine:		
1. Urine (15-20ml)	<input type="checkbox"/>	<input type="checkbox"/>

6 Total tourniquet time:
 (If tourniquet was reapplied, enter total time tourniquet was on. Note that 2 minutes is optimum.)

:

☐ am ☐ pm

Hours Minutes

minutes

Comments on phlebotomy:

9 What is the date and time you last ate or drank anything except water?

a. Date of last meal:

/

Month Day

b. Time of last meal:

:

☐ am ☐ pm

Hours Minutes

c. How many hours has participant fasted?

:

hours

(Question 5 minus Question 9b. Round down to nearest hour)

If less than 8 hours, do NOT administer OGTT, but draw blood.

LCBR Use only: Received Date:

Frozen? ☐ Yes ☐ No

Time:

25751



Page Link #


♦Page 4♦

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APPENDIX 3

Return Visit Laboratory Forms

(page 1 of 3)



HABC Enrollment ID #	Acrostic	Date Form Completed	Staff ID #
		<div style="display: flex; justify-content: space-around;"> <div> </div> <div> </div> <div> </div> </div> <div style="display: flex; justify-content: space-around; font-size: 8px;"> <div>Month</div> <div>Day</div> <div>Year</div> </div>	

RETURN VISIT PHLEBOTOMY

Bar Code Label

1 Reason for return visit:

☐ Urine collection (Go to Question #9)

☐ Fasting blood draw

☐ Other (Please specify) _____

2 Do you bleed or bruise easily?

☐ Yes ☐ No ☐ Don't know

3 Have you ever been told you have a disorder relating to blood clotting or coagulation?

☐ Yes ☐ No ☐ Don't know

4 Have you ever experienced fainting spells while having blood drawn?

☐ Yes ☐ No ☐ Don't know

5 Time at start of venipuncture?

:

am pm

Hours Minutes

Was any blood drawn?

☐ Yes ☐ No

↓

Please describe why not?

- Do NOT administer OGTT.
- Check N/A box next to cryovial #46 on Return Visit Laboratory Processing Form.

6 Time blood draw completed:

:

am pm

Hours Minutes

7 Total tourniquet time:
(If tourniquet was reapplied, enter total time tourniquet was on. Note that 2 minutes is optimum.)

minutes

Comments on phlebotomy:

8 Quality of venipuncture:

☐ Clean ☐ Traumatic

☐ Vein collapse
☐ Hematoma
☐ Vein hard to get
☐ Multiple sticks

☐ Excessive duration of draw
☐ Leakage at venipuncture site
☐ Other (Please specify:) _____

9 Were tubes filled to specified capacity?
If not, comment why.

Blood Volume/Tube	Filled to Capacity?	Comment
	Yes	No
1. Serum 10ml	<input type="checkbox"/>	<input type="checkbox"/> → _____
2. EDTA 10ml	<input type="checkbox"/>	<input type="checkbox"/> → _____
Urine:		
1. Urine (15-20ml)	<input type="checkbox"/>	<input type="checkbox"/> → _____

10 What is the date and time you last ate or drank anything except water?

a. Date of last meal:

/

Month Day

b. Time of last meal:

:

am pm

Hours Minutes

c. How many hours has participant fasted?
(Question 6 minus Question 10b. Round down to nearest hour)


hours

hours

If less than 8 hours, do NOT administer OGTT or draw blood.

LCBR Use only: Received Date: _____ Time: _____

Frozen? ☐ Yes ☐ No


21645


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APPENDIX 3

Return Visit Laboratory Forms

(page 2 of 3)



HABC Enrollment ID #

Acrostic

Date Form Completed

Month

Day

Year

Staff ID #

RETURN VISIT ORAL GLUCOSE TOLERANCE TEST

1 Has a doctor ever told you that you have diabetes or sugar diabetes?

☐ Yes ☐ No ☐ Don't know

Do you take insulin or oral hypoglycemic medications to control your diabetes? (Refer to the list to the right)

☐ Yes, insulin ☐ Yes, oral hypoglycemics ☐ No ☐ Don't know

Check N/A box next to cryovial #26 on Return Visit Laboratory Processing Form.

Verify from Baseline Health Questionnaire Q#116 or Medication Inventory Form

Do NOT administer OGTT.

Oral Hypoglycemics

Generic Name	Trade Name
Tolbutamide	Orinase
Acetohexamide	Dymelor
Tolazamide	Tolinase
Chlorpropamide	Diabinese
Glipizide	Glucotrol
Glyburide	Diabeta, Micronase
Metformin	Glucophage
Acarbose	Precose
Glicazide	Diamicron
Glimepiride	Amaryl
Troglitazone	Rezulin

2 Was the glucose tolerance test done?

☐ Yes ☐ No → Check N/A box next to cryovial #46 on Return Visit Laboratory Processing Form.

Why wasn't the glucose tolerance test done?

☐ Exclusion criteria (above)

☐ Participant refused

☐ Could not tolerate glucola

☐ Other (Please specify: _____)

3 Time glucose administered (first sip):

:

☐ am
☐ pm

Add 2 hours to time glucose administered.

Time blood draw due:

:

Hours Minutes

4 Was entire glucose drink consumed?

☐ Yes
☐ No, but more than half
☐ No, less than half - cancel 2-hour blood draw → Check N/A box next to cryovial #46 on Return Visit Laboratory Processing Form.

5 Time glucose tolerance blood drawn:

:

☐ am
☐ pm

Hours Minutes


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21214


APPENDIX 3

Return Visit Laboratory Forms

(page 3 of 3)



HABC Enrollment ID #	Acoustic	Date Form Completed	Staff ID #
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

RETURN VISIT LABORATORY PROCESSING

Bar Code Label

Time at start of processing:
 : :
 ☐ am
☐ pm

Collection Tubes	Cryo #	Vol.	Type	To	Check "X"	Problems	Collection Tubes	N/A	Cryo #	Vol.	Type	To	Check "X"	Problems
#2 Whole blood	01	0.5	W/0.5	L*	<input type="checkbox"/>	<input type="checkbox"/> H <input type="checkbox"/> P	#1 Serum		25	0.5	R/0.5	L	<input type="checkbox"/>	<input type="checkbox"/> H <input type="checkbox"/> P
#2 EDTA	02	1.0	W/2.0	L	<input type="checkbox"/>	<input type="checkbox"/> H <input type="checkbox"/> P			26	0.5	R/0.5	L	<input type="checkbox"/>	<input type="checkbox"/> H <input type="checkbox"/> P
							#8 OGTT		46	0.5	O/0.5	L	<input type="checkbox"/>	<input type="checkbox"/> H <input type="checkbox"/> P
							URINE		47	2.0	V/2.0	M	<input type="checkbox"/>	<input type="checkbox"/> H <input type="checkbox"/> P
									48	2.0	V/2.0	M	<input type="checkbox"/>	<input type="checkbox"/> H <input type="checkbox"/> P
							(acidified)		49	2.0	G/2.0	M	<input type="checkbox"/>	<input type="checkbox"/> H <input type="checkbox"/> P

L=LCBR; M=McKesson, H=Hemolyzed; P=Partial; W=white; R=red; O=orange; V=violet G=green
 *DO NOT FREEZE. To be shipped separately on wet ice.

Version 1.0, 9/2/97



APPENDIX 4
OSHA
Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens
Standard, 29 CFR 1910.1030
(15 pages)

1910.1030 - Bloodborne pathogens.

- * Standard Number: 1910.1030
- * Standard Title: Bloodborne pathogens.
- * SubPart Number: Z
- * SubPart Title: Toxic and Hazardous Substances

Produced by USDOL OSHA - Directorate of Safety Standards &
Directorate of Health Standards
Maintained by USDOL OSHA - OCIS

(a) Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) Definitions. For purposes of this section, the following shall apply:

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

"Blood" means human blood, human blood components, and products made from human blood.

"Bloodborne Pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

"Clinical Laboratory" means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

"Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

"Contaminated Laundry" means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

"Contaminated Sharps" means any contaminated object that can penetrate

the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

"Engineering Controls" means controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace.

"Exposure Incident" means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

"Handwashing Facilities" means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

"Licensed Healthcare Professional" is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

"HBV" means hepatitis B virus.

"HIV" means human immunodeficiency virus.

"Occupational Exposure" means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

"Other Potentially Infectious Materials" means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

"Parenteral" means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

"Personal Protective Equipment" is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

"Production Facility" means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

"Regulated Waste" means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

"Research Laboratory" means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

"Source Individual" means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

"Sterilize" means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

"Universal Precautions" is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

"Work Practice Controls" means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

..1910.1030(c) (c) Exposure Control. (1) Exposure Control Plan. (i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure. (ii) The Exposure Control Plan shall contain at least the following elements: (A) The exposure determination required by paragraph (c)(2), (B) The schedule and method of

implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and (C) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard. (iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e). (iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. ..1910.1030(c)(1)(v) (v) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying. (2) Exposure Determination. (i) Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following: (A) A list of all job classifications in which all employees in those job classifications have occupational exposure; (B) A list of job classifications in which some employees have occupational exposure, and (C) A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard. (ii) This exposure determination shall be made without regard to the use of personal protective equipment. (d) Methods of Compliance. (1) General. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials. ..1910.1030(d)(2) (2) Engineering and Work Practice Controls. (i) Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used. (ii) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness. (iii) Employers shall provide handwashing facilities which are readily accessible to employees. (iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible. (v) Employers shall ensure that employees

wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment. (vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

..1910.1030(d)(2)(vii) (vii) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited. (A) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure. (B) Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique. (viii) Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

(A) puncture resistant;

(B) labeled or color-coded in accordance with this standard;

..1910.1030(d)(2)(viii)(C)

(C) leakproof on the sides and bottom; and

(D) in accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure. (x) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present. (xi) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances. (xii) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited. (xiii) Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

..1910.1030(d)(2)(xiii)(A) (A) The container for storage, transport, or

shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility. (B) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard. (C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics. (xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible. ..1910.1030(d)(2)(xiv)(A) (A) A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated. (B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken. (3) Personal Protective Equipment. (i) Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used. ..1910.1030(d)(3)(ii) (ii) Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased

hazard to the safety of the worker or co-worker. When the employee makes this judgment, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future. (iii) Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided. (iv) Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee. ..1910.1030(d)(3)(v) (v) Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee. (vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible. (vii) All personal protective equipment shall be removed prior to leaving the work area. (viii) When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal. (ix) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces. (A) Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. ..1910.1030(d)(3)(ix)(B) (B) Disposable (single use) gloves shall not be washed or decontaminated for re-use. (C) Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised. (D) If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall: {1} Periodically reevaluate this policy; {2} Make gloves available to all employees who wish to use them for phlebotomy; {3} Not discourage the use of gloves for phlebotomy; and {4} Require that gloves be used for phlebotomy in the following circumstances: [i] When the employee has cuts, scratches, or other breaks in his or her skin; [ii] When the employee judges that hand contamination with blood may

occur, for example, when performing phlebotomy on an uncooperative source individual; and [iii] When the employee is receiving training in phlebotomy. ..1910.1030(d)(3)(x) (x) Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated. (xi) Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated. (xii) Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery). (4) Housekeeping. (i) General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area. ..1910.1030(d)(4)(ii) (ii) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials. (A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning. (B) Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift. (C) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination. ..1910.1030(d)(4)(ii)(D) (D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps. (E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or

processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed. (iii) Regulated Waste. (A) Contaminated Sharps Discarding and Containment. {1} Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are: [a] Closable; [b] Puncture resistant; [c] Leakproof on sides and bottom; and [d] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. {2} During use, containers for contaminated sharps shall be: [a] Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries); [b] Maintained upright throughout use; and [c] Replaced routinely and not be allowed to overfill. ..1910.1030(d)(4)(iii)(A){3} {3} When moving containers of contaminated sharps from the area of use, the containers shall be: [a] Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping; [b] Placed in a secondary container if leakage is possible. The second container shall be: [i] Closable; [ii] Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and [iii] Labeled or color-coded according to paragraph (g)(1)(i) of this standard. {4} Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury. (B) Other Regulated Waste Containment. {1} Regulated waste shall be placed in containers which are: [a] Closable; [b] Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping; [c] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and [d] Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. ..1910.1030(d)(4)(iii)(B){2} {2} If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be: [a] Closable; [b] Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping; [c] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and [d] Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. (C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories. (iv) Laundry. (A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. {1} Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use. ..1910.1030(d)(4)(iv)(A){2} {2} Contaminated laundry shall be placed and

transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions. {3} Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior. (B) The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment. (C) When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i). ..1910.1030(e) (e) HIV and HBV Research Laboratories and Production Facilities. (1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard. (2) Research laboratories and production facilities shall meet the following criteria: (i) Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens. (ii) Special Practices (A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress. (B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area. ..1910.1030(e)(2)(ii)(C) (C) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms. (D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard. (E) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment

devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench. (F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered. ..1910.1030(e)(2)(ii)(G) (G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable. (H) Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens. (I) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary. (J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal. ..1910.1030(e)(2)(ii)(K) (K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials. (L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person. (M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them. (iii) Containment Equipment. (A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols. ..1910.1030(e)(2)(iii)(B) (B) Biological safety cabinets shall be certified when installed, whenever they are moved

and at least annually. (3) HIV and HBV research laboratories shall meet the following criteria: (i) Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area. (ii) An autoclave for decontamination of regulated waste shall be available. (4) HIV and HBV production facilities shall meet the following criteria: (i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

..1910.1030(e)(4)(ii) (ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination. (iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area. (iv) Access doors to the work area or containment module shall be self-closing. (v) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area. (vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area). ..1910.1030(e)(5) (5) Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix). (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up. (1) General. (i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident. (ii) The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are: (A) Made available at no cost to the employee; (B) Made available to the employee at a reasonable time and place; (C) Performed by or under the supervision of a licensed physician or by or under the supervision of

another licensed healthcare professional; and (D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f). ..1910.1030(f)(1)(iii) (iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee. (2) Hepatitis B Vaccination. (i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons. (ii) The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination. (iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time. (iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A. ..1910.1030(f)(2)(v) (v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii). (3) Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements: (i) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred; (ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law; (A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented. ..1910.1030(f)(3)(ii)(B) (B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated. (C) Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual. (iii)

Collection and testing of blood for HBV and HIV serological status; (A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained. (B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible. (iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service; ..1910.1030(f)(3)(v) (v) Counseling; and (vi) Evaluation of reported illnesses. (4) Information Provided to the Healthcare Professional. (i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation. (ii) The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information: (A) A copy of this regulation; (B) A description of the exposed employee's duties as they relate to the exposure incident; (C) Documentation of the route(s) of exposure and circumstances under which exposure occurred; (D) Results of the source individual's blood testing, if available; and (E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain. (5) Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation. ..1910.1030(f)(5)(i) (i) The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination. (ii) The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information: (A) That the employee has been informed of the results of the evaluation; and (B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment. (iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report. (6) Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section. (g) Communication of Hazards to Employees. (1) Labels and Signs. (i) Labels. (A) Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

..1910.1030(g)(1)(i)(B) (B) Labels required by this section shall include the following legend:

BIOHAZARD

(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color. (D) Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal. (E) Red bags or red containers may be substituted for labels. (F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g). ..1910.1030(g)(1)(i)(G) (G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement. (H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated. (I) Regulated waste that has been decontaminated need not be labeled or color-coded. (ii) Signs. (A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

BIOHAZARD

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other responsible person.)

..1910.1030(g)(1)(ii)(B) (B) These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color. (2) Information and Training. (i) Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours. (ii) Training shall be provided as follows: (A) At the time of initial assignment to tasks where occupational exposure may take place; (B) Within 90 days after the effective date of the standard; and (C) At least annually thereafter. (iii) For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

(iv) Annual training for all employees shall be provided within one year of their previous training. (v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created. ..1910.1030(g)(2)(vi) (vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used. (vii) The training program shall contain at a minimum the following elements: (A) An accessible copy of the regulatory text of this standard and an explanation of its contents; (B) A general explanation of the epidemiology and symptoms of bloodborne diseases; (C) An explanation of the modes of transmission of bloodborne pathogens; (D) An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan; (E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials; (F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment; ..1910.1030(g)(2)(vii)(G) (G) Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment; (H) An explanation of the basis for selection of personal protective equipment; (I) Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge; (J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials; (K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available; (L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident; (M) An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and ..1910.1030(g)(2)(vii)(N) (N) An opportunity for interactive questions and answers with the person conducting the training session. (viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address. (ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements. (A) The employer shall assure

that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV. (B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV. (C) The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

..1910.1030(h) (h) Recordkeeping. (1) Medical Records. (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020. (ii) This record shall include: (A) The name and social security number of the employee; (B) A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2); (C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3); (D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and (E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D). (iii) Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are: ..1910.1030(h)(1)(iii)(A) (A) Kept confidential; and (B) Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law. (iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020. (2) Training Records. (i) Training records shall include the following information: (A) The dates of the training sessions; (B) The contents or a summary of the training sessions; (C) The names and qualifications of persons conducting the training; and (D) The names and job titles of all persons attending the training sessions. (ii) Training records shall be maintained for 3 years from the date on which the training occurred. (3) Availability. (i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying. ..1910.1030(h)(3)(ii) (ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee

representatives, to the Director, and to the Assistant Secretary. (iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020. (4) Transfer of Records. (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h). (ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period. (i) Dates. ..1910.1030(i)(1) (1) Effective Date. The standard shall become effective on March 6, 1992. (2) The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992. (3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992. (4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992. [56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996]

APPENDIX 5
Phlebotomy Checklist

Blood Collection Tray Checklist

Per Tray:

- Ñ 10 21G Butterfly needles with Luer Adapters
- Ñ 10 Alcohol Swabs
- Ñ 15 Band-Aids
- Ñ 15 Gauze pads
- Ñ 5 Vacutainer holders
- Ñ complete set of extra, unlabeled collection tubes
- Ñ 2 Tourniquets
- Ñ 1 Smelling salts
- Ñ 1 Timer or stopwatch
- Ñ 2 Pencils/pens
- Ñ Latex gloves
- Ñ 1 Hemostats
- Ñ 1 Adhesive tape
- Ñ 1 Scissors

~10 min before draw:

- Ñ 1 styrofoam ice bath filled with ice

Per participant:

- Ñ 1 Blood tube rack with 9 draw tubes labeled and numbered.
- Ñ 1 Health ABC Phlebotomy/Processing Form

At the Phlebotomy Station:

- Ñ Basin
- Ñ Cold cloth
- Ñ Tube mixer
- Ñ Biohazard containers
- Ñ Needle/Sharps container
- Ñ Paper towels

APPENDIX 6

March 13, 1997

Abe Friedman, M.D.
5845 Centre Avenue
Pittsburgh, PA 15213

Dear Dr. Friedman:

On June 1, 1997, we performed a surveillance visit on your patient _____ at the Health ABC Clinic. [A fasting and 2-hour OGTT glucose were obtained and the results of the fasting glucose are 76 mg/dL, and the 2-hour glucose was 40 mg/dL. (Alert values are <50 mg/dL or >500 mg/dL.)] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at _____. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd
Coordinator of Clinical Studies

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